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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,343	10/02/2002	Naoyuki Kamata	2443	1372

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EXAMINER	
MCKANE, ELIZABETH L	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,343	KAMATA, NAOYUKI	
	Examiner	Art Unit	
	Leigh McKane	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *041702,060502*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 3, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck (U.S. Patent No. 5,352,462) in view of Savello et al (U.S. Patent No. 5,368,869).

Beck teaches isolation, purification, and use of a milk anti-inflammatory factor. See col.9, line 54 to col.10, line 43. Beck is silent with respect to the further step of sterilizing/pasteurizing the milk anti-inflammatory factor.

Savello et al teaches that it was known in the art at the time of the invention to pasteurize milk products using low-temperature, long-time heating at 63 °C for 30 minutes. See col.7, lines 49-51. This treatment is disclosed by Savello et al to kill most microorganisms. It would have been obvious to use the pasteurization treatment of Savello et al on the milk anti-inflammatory factor of Beck because it has been shown to be effective on milk products. Moreover, one would have found it obvious to add the further pasteurization step to the method of Beck, since the

product produced by the method of Beck is destined for use as pharmaceutical to be administered to individuals with various inflammatory conditions. The presence of microorganisms in a pharmaceutical of this type would be unacceptable because of the harm they could cause.

4. Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck in view of Savello et al and Greenblatt et al (U.S. Patent no. 5,772,999).

Beck teaches isolation, purification, and use of a milk anti-inflammatory factor. See col.9, line 54 to col.10, line 43. Beck is silent with respect to the further step of sterilizing/pasteurizing the milk anti-inflammatory factor or to using the purified milk anti-inflammatory factor in a food or drink.

Savello et al teaches that it was known in the art at the time of the invention to pasteurize milk products using low-temperature, long-time heating at 63 °C for 30 minutes. See col.7, lines 49-51. This treatment is disclosed by Savello et al to kill most microorganisms. It would have been obvious to use the pasteurization treatment of Savello et al on the milk anti-inflammatory factor of Beck because it has been shown to be effective on milk products. Moreover, one would have found it obvious to add the further pasteurization step to the method of Beck, since the product produced by the method of Beck is destined for use as pharmaceutical to be administered to individuals with various inflammatory conditions. The presence of microorganisms in a pharmaceutical of this type would be unacceptable because of the harm they could cause.

Greenblatt et al discloses the known inclusion of a hyperimmunized milk product in foods such as yogurt, ice cream, and beverages. See col.8, lines 22-35. As Beck already teaches that the milk anti-inflammatory factor may be administered orally as tablets, pills, syrups, and

suspensions, one of ordinary skill in the art would have found it obvious to include the milk anti-inflammatory factor in other forms used for oral administration of a milk-based pharmaceutical.

5. Claims 2, 5, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck in view of Lindquist (U.S. Patent No. 6,117,470).

Beck teaches isolation, purification, and use of a milk anti-inflammatory factor. See col.9, line 54 to col.10, line 43. Beck is silent with respect to the further step of sterilizing/pasteurizing the milk anti-inflammatory factor.

Lindquist evidences that it was known at the time of the invention to remove bacteria (i.e. sterilize) from milk using microfilters having a pore size of 0.2-1.0 μm. See col.1, lines 23-25. It would have been obvious to employ the sterilization method disclosed by Lindquist to sterilize the milk anti-inflammatory factor of Beck because it has been shown to be effective in removing most bacteria. Moreover, one would have found it obvious to add the further sterilization step to the method of Beck, since the product produced by the method of Beck is destined for use as pharmaceutical to be administered to individuals with various inflammatory conditions. The presence of microorganisms in a pharmaceutical of this type would be unacceptable because of the harm they could cause.

6. Claims 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck in view of Lindquist and Greenblatt et al.

Beck teaches isolation, purification, and use of a milk anti-inflammatory factor. See col.9, line 54 to col.10, line 43. Beck is silent with respect to the further step of sterilizing/pasteurizing the milk anti-inflammatory factor or to using the purified milk anti-inflammatory factor in a food or drink.

Lindquist evidences that it was known at the time of the invention to remove bacteria (i.e. sterilize) from milk using microfilters having a pore size of 0.2-1.0 μm. See col.1, lines 23-25. It would have been obvious to employ the sterilization method disclosed by Lindquist to sterilize the milk anti-inflammatory factor of Beck because it has been shown to be effective in removing most bacteria. Moreover, one would have found it obvious to add the further sterilization step to the method of Beck, since the product produced by the method of Beck is destined for use as pharmaceutical to be administered to individuals with various inflammatory conditions. The presence of microorganisms in a pharmaceutical of this type would be unacceptable because of the harm they could cause.

Greenblatt et al discloses the known inclusion of a hyperimmunized milk product in foods such as yogurt, ice cream, and beverages. See col.8, lines 22-35. As Beck already teaches that the milk anti-inflammatory factor may be administered orally as tablets, pills, syrups, and suspensions, one of ordinary skill in the art would have found it obvious to include the milk anti-inflammatory factor in other forms used for oral administration of a milk-based pharmaceutical.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (6:30 am-4:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leigh McKane

Leigh McKane
Primary Examiner
Art Unit 1744

elm
23 March 2005